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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,890	10/06/2008	Yatendra Kumar	RLL-509US	7133
26815	7590	10/12/2010		
Ranbaxy Inc. Intellectual Property Department 600 College Road East PRINCETON, NJ 08540			EXAMINER NOLAN, JASON MICHAEL	
			ART UNIT 1626	PAPER NUMBER
			NOTIFICATION DATE 10/12/2010	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

general.ip.mailbox@ranbaxy.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/549,890	<b>Applicant(s)</b> KUMAR ET AL.	
	<b>Examiner</b> JASON M. NOLAN	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,5-17,22,24-35 and 37-46 is/are allowed.
- 6) ☒ Claim(s) 2-4 and 47 is/are rejected.
- 7) ☒ Claim(s) 18-21,23 and 36 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This Office Action is responsive to Applicant's Transmittal of New Application, filed September 16, 2005. Claims 1-47 are pending.

#### ***Priority***

This application is a 371 of PCT/IB04/03789, having a filing date of October 6, 2008. Claim for priority in the Oath is acknowledged. However, the foreign priority document, INDIA 491/DEL/2004 (filed on March 17, 2004), has not been received. The Examiner requests for Applicant to provide the priority document in order to complete the record in the file.

#### ***Information Disclosure Statement***

Applicant's information disclosure statements (IDS), filed on October 9, 2008 and May 6, 2009 have been considered. Please refer to Applicant's copies of the 1449 submitted herein.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1626

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Obviousness under 35 U.S.C. § 103 is a question of law, but is based on underlying facts of each case. The Supreme Court stated that an invention may be found obvious if it would have been obvious to a person having ordinary skill to try a course of conduct:

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

*KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

Although a combination of relevant options in a particular art may be obvious to try, there are instances where an invention would not have been obvious to try:

1) When the inventor would have had to try all possibilities in a field unreduced by direction of the prior art. In other words, when "what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful" an invention would not have been obvious. *In re O'Farrell*, 853

F.2d 894, 903 (Fed. Cir. 1988). This is another way to express the *KSR* prong requiring the field of search to be among a “finite number of identified” solutions. 550 U.S. at 421.

2) An invention is not obvious to try where vague prior art does not guide an inventor toward a particular solution. A finding of obviousness would not obtain where “what was ‘obvious to try’ was to explore a technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.” *O’Farrell*, 853 F.2d at 903. This expresses the same idea as the *KSR* requirement that the identified solutions be “predictable.” 550 U.S. at 421.

Claim 2 is rejected under 35 U.S.C. § 103(a) as being unpatentable over US 6,528,660 (IDS; “the ‘660 patent”), WO 97/03959 (IDS) and US 5,273,995 (IDS; “the ‘995 patent”) in view of PAVIA *ET AL.* INTRODUCTION TO ORGANIC LABORATORY TECHNIQUES 1990, pp. 577-596.

*1. Determining the scope and contents of the prior art –*

The ‘995 patent discloses that atorvastatin may be crystallized/precipitated with acetone/water. See Example 11, col. 16.

WO 97/03959 discloses that atorvastatin may be crystallized/precipitated from a mixture of methanol and water. See Examples.

The ‘660 patent discloses that atorvastatin may be crystallized/precipitated with tetrahydrofuran/water mixture.

2. *Ascertaining the differences between the prior art and the claims at issue* – those references do not disclose THF.

3. *Resolving the level of ordinary skill in the pertinent art* – the level of ordinary skill in the art may be found by inquiring into: (1) the type of problems encountered in the art; (2) prior art solutions to those problems; (3) the rapidity with which innovations are made; (4) the sophistication of the technology; and (5) the education level of active workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc.*, 807 F.2d 855, 962 (Fed. Cir. 1986). All of those factors may not be present in every case, and one or more of them may predominate. *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983).

Based on the typical education level of active workers in the field of organic chemistry, as well as the high degree of sophistication required to solve problems encountered in the art, the Examiner finds that a person of ordinary skill in the art would have at least a college degree in the field of organic chemistry and at least four years of work experience, i.e. a masters or doctorate level scientist.

4. *Considering objective evidence present in the application indicating obviousness or nonobviousness* – none.

*Conclusion* – the Federal Circuit stated "[o]bviousness does not require absolute predictability of success . . . all that is required is a reasonable expectation of success." *O'Farrell* at 903-904. *In the instant case*, the prior art cited above supports the conclusion that a person of ordinary skill in the art, at the time of invention, would have been motivated to try known options within their technical grasp in the art.

In this case, those options include the plethora of solvents available to those in the art. One seeking to produce a crystal form will attempt a series of solvents and mixtures thereof. See generally, Pavia *et al.*, which teaches basic techniques and selection of solvent.

Because the specification fails to produce evidence of unexpected results, a long-felt industrial need, or other secondary considerations, the Examiner concludes that one of ordinary skill in the art would have been motivated to arrive at the instant claimed invention with an expectation of success.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**1.** Claim 47 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

**2.** A claim is indefinite when it contains words or phrases whose meaning is unclear. The lack of clarity could arise where a claim refers to “said lever” or “the lever,” where the claim contains no earlier recitation or limitation of a lever and where it would be unclear as to what element the limitation was making reference. MPEP 2173.05(e).

*In the instant application*, Claims 3 & 4 are rejected because Claim 2 recites the limitation "the acid." Claim 3 is dependent upon Claim 2; however, Claim 2 does not recite "an acid." Therefore, there is insufficient antecedent basis for this limitation in the claim.

### ***Claim Objections***

**1.** Claims 18, 20, 21, 23, & 36 are objected to under 37 CFR § 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further considered on the merits.

Claims 18, 20, 21, & 23 cannot depend from another multiple dependent claim.

Claim 36 should refer to other claims in the alternative only.

**2.** Claims 19-21 are objected to as being dependent upon a rejected base claim (Claim 2), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.



***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason M. Nolan whose telephone number is (571) 272-4356 and e-mail is [Jason.Nolan@uspto.gov](mailto:Jason.Nolan@uspto.gov). The examiner can normally be reached Monday - Friday (9:00AM - 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, may be contacted at [Joseph.McKane@uspto.gov](mailto:Joseph.McKane@uspto.gov) or (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system, (Private PAIR or Public PAIR). Status information for unpublished applications is available through Private PAIR only. For information about the PAIR system, see <http://pair-direct.uspto.gov>. For questions on Private PAIR system, contact the Electronic Business Center at (866) 217-9197.

/Jason M. Nolan/

Examiner, Art Unit 1626